High Sensitivity, Low Complexity, Multiplexed Diagnostic Devices

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The official link for this solicitation is:
http://www.acq.osd.mil/osbp/sbir/solicitations/sbir20152/index.shtml

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Description:
The U.S. Department of Defense requires infectious disease in vitro diagnostic (IVD) capabilities that are operationally suitable for use in far forward military environments and operationally effective versus a wide range of threats. Current single use disposable Lateral Flow Immunoassay-based diagnostic tests have many desirable operational suitability characteristics (low cost, minimal training, lightweight, results in 15 minutes, eye readable results, and long shelf life at room temperature) but lack sufficient sensitivity to be clinically useful for most infectious diseases. Current nucleic acid amplification-based diagnostic tests provide adequate sensitivity for some diseases but are slow (>30 minutes), more complex, are not compatible with many host response biomarker-based diagnostic approaches and have a high cost per test. The High Sensitivity, Low Complexity, Multiplexed Diagnostic Devices topic seeks to develop novel approaches that will fundamentally improve sensitivity while maintaining desirable operational suitability characteristics. Furthermore, novel approaches will be needed to incorporate multiple analytical approaches into a single platform technology to provide clinical utility across a broad range of etiological agents (i.e., intracellular organisms, parasites, etc.), diseases and clinical sample types and to provide information to support force health protection decision making. PHASE I: Describe the specific technical approaches that would be pursued for achieving better than state of the art clinical sensitivity (≥90%) for acute infections (testing occurs within the first 168 hours after symptom on-set or pre-symptomatically) in an operationally suitable platform for the representative etiological agents/diseases: • Yersinia pestis

/ Plague (Gram-negative coccobacillus) • Brucella spp. / Brucellosis (Intracellular, Gram-negative bacteria) • Alpha viruses / Venezuelan equine encephalitis, Chikungunya (Single stranded RNA) • Dengue virus with serotype identification / Dengue Fever (single stranded RNA virus) • Variola major / Smallpox (DNA virus) The five diseases listed are representative of a larger set of diseases of operational concern to the U.S. military that would be pursued if selected for Phase III transition. One or more of the representative diseases would be selected as the basis for prototype development in Phase II depending on the specific approach proposed. Within Phase I these five representative diseases serve as the basis for offerors to illustrate the innovative elements of their proposed technical approach when applied to a specific real-world problem. For disease specific tests, the description of the technical approach entails a detailed description of assay designs (bio-recognition elements), signal amplification and transduction techniques, selected sample types (least invasive clinical sampling), and sample preparation techniques (if any) for a specific diagnostic intended use that illustrates the contractor’s understanding of the disease, the diagnostic problem, and improvements over the current state of the art for the same market. The description should provide details how sufficient inclusivity and specificity will be obtained to inform treatment decisions. Syndromic approaches (through multiplexing) add significantly to clinical utility. Provide an analysis of the envisioned technical approach with respect to the Clinical Laboratory Improvement Act (CLIA) guidelines for CLIA-waived status. PHASE II: For one or more of the test types investigated in Phase I, develop and deliver prototype IVD device and pilot lot assays (if applicable to the system design) to the Government for independent evaluation. Complete pre-submission meetings with the FDA to inform inclusivity, specificity and syndromic approaches and intended use for the test and CLIA-waived clinical trial design. The degree of innovation will be measured by the offeror’s ability to achieve a high clinical sensitivity for a broad range of disease and sample types while retaining operationally desirable characteristics (cost